HT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,802	12/28/2001	Kunal Saha	28335/37036 US	2908

4743 7590 04/28/2004

MARSHALL, GERSTEIN & BORUN LLP
6300 SEARS TOWER
233 S. WACKER DRIVE
CHICAGO, IL 60606

EXAMINER
STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,802	SAHA, KUNAL	
	Examiner	Art Unit	
	Jeffrey Stucker	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004 and 09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *2,3,5-28,30-38 and 40-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,29 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Group I filed 1/06/04 is acknowledged. The traversal is on the grounds that:

1) Groups I and II should be rejoined because they involve the same prior art and the search would be relatively easy because existing search engines permit a search of the translation of known sequence;

2) Groups I and III should be rejoined because if the peptides of Group I are novel, then the antibodies of Group III should also be novel and that it would not be a serious burden on the examiner to do one search;

3) Groups I and IV should be rejoined because the method of claim 34 depends from a claim in Group I and remind that applicant is entitled to rejoinder of claims to methods and to facilitate efficient examination, the small number of claims in Group IV and their relatedness to Group I suggest that there will be no serious burden involved;

4) Groups I and VI should be rejoined because it would be efficient to examine both groups together, applicant reminds that the Office should rejoin method claims with allowed product claims, should there be any, and again argues that the small number of claims suggest there will be no serious burden involved.

None of this is found persuasive because:

If all of the groups with a "small number of claims" were rejoined, nearly the entire set of claims would be examined and applicant would improperly be getting an examination of more than one invention in the application for only one filing fee.

1) The Office has a policy of searching only one sequence per application. See under 1192 O.G. 68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO. Even though some search engines may automatically translate between protein and nucleic acid sequences, each is still a separate and distinct search.

2) The antibodies require additional searching and consideration. Further, even if the claimed protein were allowable, it does not follow that the antibodies would be free of the art. For example, CD4 tropic antibodies may cross react or naturally occurring antibodies may be specific for the claimed protein.

3) and 4) Rejoinder may be possible at some future point if the product is eventually found to be patentable. Guidance on treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March

26, 1996 at 1184 O.G. 86. The product and the methods are distinct for the reasons given in the Restriction requirement.

Applicant's attention is drawn to some obvious typographical errors in the restriction requirement that were repeated in applicant's response.

Group I: should be claims 1-10, 29, and 39-**49** (gp120) and

Group X: should be claims **50-55** (gp41); there is no claim 56.

Therefore, the proper listing of claims in Group I, gp120 polypeptides, is 1-10, 29, and 39-49. In addition, applicant elected SEQ ID NO:10 as the elected sequence to examine. In view of this, claims 2, 3, 5-10 are withdrawn from consideration. Further, claims 40-49 are directed to sequences that do not fall within the elected sequence and are likewise withdrawn from consideration.

In summary, claims 1-55 are pending, claims 2, 3, 5-28, 30-38, and 40-55 are withdrawn from consideration as being drawn to non-elected inventions, and claims 1, 4, 29, and 39 are examined and rejected.

The requirement is still deemed proper and is therefore made FINAL.

A review of the parent provisional application indicates that applicant is not entitled to priority back to the filing date of the provision application for 96USHIPS9-T8 related sequences because they are not supported by the disclosure of the provisional application. Therefore, the priority date for the claimed SEQ ID NO: 10 is the instant filing date.

It appears from the specification at page 18 that color figure(s) were submitted.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is meant by "set out in". Is this open or closed language?

In claim 29, "polypeptide" should be plural.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 29, and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)

the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The nature and breadth of the invention is an isolated HIV-1 gp120 polypeptide that is tropic for CD8 and a pharmaceutical composition comprising HIV-1 gp120 polypeptide that is tropic for CD8. The relative skill of those in the art is high. The state of the prior art says little in regards to gp120 peptides that are tropic for CD8. In fact, the prior art indicates that one would not expect HIV-1 gp120 to be tropic for CD8. For example, Kaneko et al. (J. of Virol., IDS reference C6) explicitly teaches that HIV-1 gp120 cannot bind to CD8 molecules. Further, Patropoulos et al. (US 2002/0182592 A1) discloses prophetic examples of methods of detecting CD8 tropic viruses. See example 4 and paragraphs 0231 and 0243. However, there is no evidence in the document that such viruses actually exist. This would lead one of ordinary skill in the art to predict that it is not within the skill of the artisan to make

and use an isolated HIV-1 gp120 polypeptide that is tropic for CD8 beyond the specific examples disclosed without an undue amount of experimentation. The amount of guidance presented is in regards to general teachings about HIV-1 gp120 binding to CD4+ and/or CD8+ cells. There are some sequence alignments disclosed from which applicant conjectures that certain mutation(s) confer CD8 tropism. However, there is no evidence of record to indicate that any such correlation demonstrates causality, i.e., CD8 tropism and, therefore, have not taught which region or mutation is required for CD8 tropism. Further, there is no specific guidance concerning a pharmaceutical composition comprising the claimed protein. The working examples are limited to infective viruses, *not isolated* gp120. This is important because there may be support for a *virus* that specifically infects CD8 cells but there is no support for an isolated gp120 that infects CD8 cells because the infection is a multi-component event involving a complex of gp120, gp41, a cellular receptor (usually CD4, but purportedly CD8 in this instance) and a cellular coreceptor. The quantity of experimentation necessary is high because of the immense number of HIV-1 isolates which are in existence and are constantly evolving as well as a variable coreceptor usage by the virus and coreceptor display by cells. Further, there is no specific

disclosure in the specification of how to make and use the claimed composition as a pharmaceutical composition.

The instant invention, based on the evidence as a whole, in light of the factors articulated by the court in *In re Wands*, lacks an enabling disclosure.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hoxie et al. (WO 00/71561 A1, IDS ref. B1) teaches CD4 independent HIV envelope protein but dies not appear to teach CD8 tropic HIV envelope protein.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

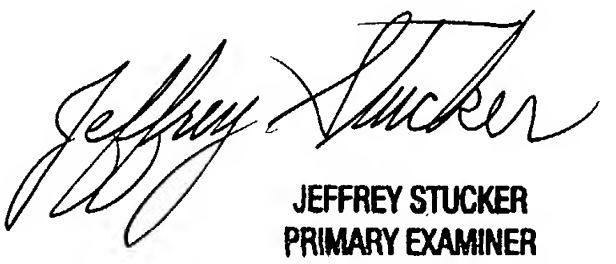
The Group 1600 Official Fax number is: (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.



JEFFREY STUCKER
PRIMARY EXAMINER